

REMARKS

This is in response to the Final Office Action mailed March 18, 2010. Applicants herewith petition for a two month extension of time. Claims 1-21 are pending in the application. Claims 1-12, 15 and 16 are withdrawn from consideration. Claims 13, 17 and 20 are canceled without prejudice or disclaimer. Claims 14 and 21 are amended. With entry of this Amendment, claims 14, 18, 19 and 21 will be active for consideration.

I. Claim Rejections – 35 U.S.C. § 103

Claims 13, 14, and 17-21 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Pflaum (US 6740775) in view of Kofler et al. (US 6511972).

According to the Examiner, Pflaum teaches pharmaceutical compositions of the sodium salt of pravastatin in a crystalline form and methods of making them (claims 1-19) and directs applicants' attention to Figure 2. The Examiner also states that Pflaum teaches methods of making the pravastatin in the presence of ethanol or methanol (column 4, lines 26-52), and a process of preparing the sodium salt of pravastatin using open language (claim 6). Kofler is cited for teaching using microcrystalline cellulose, such as Avicel PH 112 having a particle size from 20 to 100 microns for capsule and tablet formulations (column 2, lines 10-15). At page 9, the Examiner reminds applicants that the "patentability of a product does not depend on its method of production" citing *In re Thorpe*, 227 USPQ 964, 966 (Fed Cir. 1985). The Examiner also stated that no unexpected results have been shown.

Applicants respectfully traverse this rejection. In further response, however, applicants point out that this rejection is moot with regard to claim 13 and claims that depend therefrom in view of the cancellation of these claims. Claim 14 has been amended. Support for this amendment can be found in paragraph [0069]. With regard to amended claim 14, applicants urge that the stability demonstrated with the claimed composition is unexpected. Additionally, nothing in Pflaum would suggest that the disclosed "Lek" compound would remain stable for one month. Applicants have argued previously that Pflaum is not concerned with any particular formulation, rather it is directed to the polymorph *per se* and any reference to pharmaceutical formulations is generic. Therefore, nothing in Pflaum inherently teaches a composition of claim 14 or suggests the problem of the compound being unstable when formulated with certain components. Kofler discloses microcrystalline cellulose but also does not concern the problem of the "Lek" polymorph's instability when formulated in a particular manner and therefore provides no explicit guidance toward a formulation having the degree of stability recited in claim 14.

The Examiner also has rejected claims 13, 14 and 17-21 under 35 USC § 103 as being obvious over Keri (WO 01/43723) in view of Kofler. According to the Examiner, the difference between the instant application and Keri is that Keri does not expressly teach adding microcrystalline cellulose that has an average particle size of from 10 to 200 microns and a weight ratio of pravastatin to microcrystalline cellulose of greater than 1 and/or the weight ratio pravastatin sodium to liquid that is greater than 1.0 to obtain a stabilized pharmaceutical composition. This deficiency is said to be cured by Kofler. The

Examiner also states that in the absence of some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of the invention. The examiner also asserts that the composition would be intrinsically stabilized against converting into one exhibiting peaks having half value widths of significant peaks above 2 degree 2 Theta in the absence of evidence to the contrary. Applicants respectfully traverse this rejection, which is moot with regard to claim 13 and claims that depend from claim 13.

With regard to claim 14, applicants again point out that this claim has been amended to recite that a sample of the composition subjected to accelerated stability testing at 60 degrees centigrade remains stable after one month after being prepared. Support for this recitation can be found in paragraph [0069]. Applicants assert that the recited stability would have been unexpected based upon the prior art teachings. Applicants also assert that the Examiner's rejection is based on one of inherency. That is, the Examiner assumes that the disclosed compounds would be the same as applicants' and that the recited ratios and ingredients are mere optimizations. This assessment ignores the fact that the cited art does not motivate one to make the optimizations because neither reference acknowledges that while a particular polymorph of pravastatin may be stable alone, such polymorph may be rendered unstable when formulated by wet granulation. Applicants' invention addresses this unrecognized problem.

In view of the above arguments and amendment, applicants respectfully request the Examiner to reconsider and withdraw the rejection over Keri combined with Kofler.

II. Double Patenting Rejection

The Examiner has rejected claims 13, 14 and 17-21 for obviousness-type double patenting over claims 1, 7, 14, 17, 18, 19, 25, 32, 33 and 39 of Kerc (US Patent No. 6,680,341) in view of Pflaum (US Patent No. 6740775) and Kofler. Applicants respectfully traverse this rejection, which is moot with regard to claim 13 and claims that depend therefrom.

Nothing in claims 1, 7, 14, 17, 18, 19, 25, 32, 33 and 39 of Kerc would direct the skilled artisan to the invention of claim 14, as amended, and one could not arrive at the claimed invention by combining the teachings of Pflaum '775 and Kofler, for reasons discussed above. Accordingly, applicants respectfully request the Examiner to reconsider and withdraw this rejection.

The Examiner also rejects claims 13, 14 and 17-21 for obviousness-type double patenting over claims 1, 12, 13 and 17 of Pflaum (US Patent No. 6,531,507) in view of Pflaum (US Patent No. 6,740,775) and Kofler. Applicants respectfully traverse this rejection, which is moot with regard to claim 13 and claims that depend therefrom. With regard to claim 14, nothing in claims 1, 12, 13 and 17 of Pflaum '507, which solve the problem of stabilizing the composition by using buffering substance or basifying substance, directs the skilled artisan toward the specific ingredients and ratios recited in claim 14 or the one month stability achieved with by such compositions. The deficiencies of Pflaum '775 and Kofler have been discussed above and are applicable to the non-obviousness of

the claims in view of Pflaum '775.

In view of these arguments and the above amendment, applicants respectfully request the Examiner to reconsider and withdraw these rejections for obviousness-type double patenting.

CONCLUSION

In view of the above amendment and arguments, applicants believe the pending application is in condition for allowance. Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing Atty. Docket No. 029489-00023.

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Respectfully submitted,

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